

**NHS LINCOLNSHIRE in association with**  
**UNITED LINCOLNSHIRE HOSPITALS TRUST**

**SHARED CARE GUIDELINE:**

**Nabilone in the management of chronic neuropathic pain that has failed to respond to other first and second line treatments.**

**General Principles**

**Shared Care Responsibilities:**

In its guidelines on responsibility for prescribing (circular EL (91) 127) between hospitals and general practitioners, the Department of Health has advised that legal responsibility for prescribing lies with the doctor who signs the prescription. (*BNF 60*, September 2010, pg.2)

**Aims:**

- (1) The aim of shared care guidelines is to provide information and/or guidance to GPs and hospital staff relating to the potentially complex implications of sharing patient care for a specific drug between primary and secondary/tertiary care.
- (2) Specific shared care guidance should be available for any high cost drug, high-risk drug therapy or device that may be prescribed for a patient following specialist referral. Such guidance will only be produced where shared care is considered an appropriate option.
- (3) Each guideline will include a clear statement of the responsibilities of both the GP and the specialist unit within the overall provision of the treatment to the patient.
- (4) Shared care guidelines will ensure that the GP has sufficient information available to undertake to prescribe a specialist treatment if s/he so wishes. It is not the intention of these guidelines to insist that GPs prescribe such treatment and any doctor who does not wish to accept clinical or legal responsibility to prescribe such a drug is under no obligation to do so. Nonetheless the development of a shared care guideline will only be undertaken within the context of a broad acceptance between Lincolnshire Prescribing and Clinical Effectiveness Forum (PACEF) and secondary/tertiary care that GP prescribing of such a treatment is appropriate within the constraints of formal shared care. Any drug approved for the development of a shared care guideline will automatically be classified as amber on the Lincolnshire Traffic Lights List and, if high-cost, will be supported financially through the High Cost Drugs Reserve. Thus there should be no financial reason why a GP should be deterred from prescribing a high cost drug under a shared care guideline.

**Further copies**

Further copies of any guidelines in this series are available from PCT Prescribing Advisers.

**Date of Issue: January 2011**

**Review Date: January 2013**

### **Drug Details**

Approved Name: Nabilone

Brand Name:

Form and Strength: 1mg capsules

### **Specialist Responsibilities**

The specialist secondary/tertiary care service will:

1. Send a letter to the GP suggesting that shared care is agreed for this patient.
2. Ensure that the patient receives initial supplies of nabilone from the hospital until the GP formally agrees to share care.
3. Provide a comprehensive assessment of the patient.
4. Discuss treatment options with the patient to include an explanation of the unlicensed use of nabilone for the treatment of neuropathic pain obtaining consent to treatment.
5. Ensure that the patient is aware of possible side effects on mood and behavioural effects of nabilone.
6. Initiate treatment with nabilone or provide the GP with clear instructions as to the initial dose of including details of any dose titration that might be required and when the patient will next be reviewed in clinic.
7. Periodically review the patients clinical condition
8. Communicate promptly any changes in nabilone dose or any other ongoing pain clinic intervention to the GP.
9. Have a mechanism in place to receive rapid referral of a patient from the GP in the event of deteriorating clinical condition.
10. Follow up any adverse drug reactions reported by the GP and report back to the GP.
11. Provide support to the GP and advice if treatment needs to be discontinued.

### **GP Responsibilities**

The GP will:

1. Notify the consultant in writing, without undue delay, if they agree to share care
2. Initiate treatment with nabilone according to written instructions provided by the specialist service or continue to prescribe at the dose initiated by the specialist.
3. Monitor the patients overall health and wellbeing.
4. Monitor the patient for adverse drug reactions and remain vigilant to the risk of potential drug interactions.
5. Carry out any investigations that are communicated and deemed appropriate.
6. Refer back to the specialist if condition deteriorates as advised by specialist service.
7. Discontinue treatment (where necessary) on the advice of the specialist

### **Referral Criteria**

1. Patients will have been stabilized on nabilone on an appropriate dose unless GP has agreed to initiate treatment according to instructions provided by the specialist service.
2. The specialist will have carried out an assessment of efficacy

### **Licensed Indications**

Nabilone is licensed for nausea and vomiting caused by cytotoxic chemotherapy unresponsive to conventional anti-emetics. It is not licensed as an analgesic. Nabilone is prescribed by the Chronic Pain Management Team outside of product license.

Indications for initiating treatment:

Adults with distressing, intractable, neuropathic pain that has failed to respond to:

1. First line medications including: opioids (including strong opioids), antidepressants (e.g. amitriptyline) and anticonvulsants (e.g. gabapentin).
2. Other reasonable treatments under the care of the pain clinic (e.g. injectable therapies, complementary therapies and other treatments such as TENS).

### **Recommended Dosage and Administration**

Usually up to 1mg twice a day. Some patients may require up to 2mg twice daily although this would be regarded as unusual. Some patients find very low doses beneficial (e.g. 0.5mg per day; this dosage requires the division of one capsule).

### **Background Pharmacology**

Nabilone is a synthetic cannabinoid.

### **Preparations Available**

1mg capsules.

Nabilone is not available from standard pharmaceutical wholesalers; dispensing practices and community pharmacies will need to source directly from the manufacturer.

Order contact details are:

Creo Pharma Ltd

Felsted Business Centre

Cock Green

Felsted

Essex

CM6 3LY

TEL : 0844 879 3188

Fax: 01371 822044

csp@creopharma.com

### **Adverse Effects**

Drowsiness, vertigo, euphoria, dry mouth, ataxia, visual disturbance, concentration difficulties, sleep disturbance, dysphoria, hypotension, headache and nausea; also confusion, disorientation, hallucinations, psychosis, depression, decreased coordination, tremors, tachycardia, decreased appetite and abdominal pain.

Patients should be made aware of possible changes of mood and other adverse behavioural effects.

For full list of reported adverse effects refer to SPC.

### **Drug Interactions**

There is an increased sedative effect when nabilone is given with hypnotics, anxiolytics or alcohol.

Nabilone should be administered with caution to patients who are taking other psychoactive drugs or CNS depressants.

### **Precautions and Contraindications**

Nabilone is contra-indicated in patients with a known allergy to cannabinoid agents and in those with severe hepatic impairment.

There are no studies of nabilone use in pregnancy and breast feeding. Manufacturer recommends that nabilone should not be given to nursing mothers and only should be used in pregnancy if the benefits outweigh the potential risks.

Caution should be exercised in those with a history of psychiatric disorder including manic-depressive illness and schizophrenia, adverse effects on mental state can persist for 48-72 hours after cessation of treatment

Nabilone may elevate supine and standing heart rates and cause postural hypotension and the manufacturer advises it should be used with caution in the elderly and in patients with hypertension and heart disease.

Nabilone is an abusable substance and should be used with caution in patients with a history of drug or substance abuse.

Nabilone may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as operating machinery or driving a car. Patients should be advised accordingly.

### **Monitoring**

Ongoing review will be provided by the Chronic Pain Management Team. GPs can refer patients back to the Team for review on request

### **Indication of Likely Cost of Therapy in Primary Care**

28 days supply at 1mg twice daily £352.35 annual cost - £4,581

28 days supply at 2mg twice daily £704.70 annual cost - £ 9,161

## **Information Given to the Patient**

### **Contact Details**

Pilgrim Hospital, Boston

Pain Management Clinic Secretaries – 01205 446612

Lincoln County Hospital, Lincoln

Pain Management Clinic Secretaries – 01522 573691

Or

Pain Management Nurse Specialist – 01522 512512 ext 3717

### **References**

1. BNF 60 September 2010.
2. SPC nabilone 1mg capsules Meda Pharmaceuticals . Last updated 2nd September 2009, accessed through eMC website on 31<sup>st</sup> December 2010.

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